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K050663

10.0 Traxyz Medical Inc. TraxyLoc™-1 System 510(k) Summary

APR 8 2005

Company:

Traxyz Medical, Inc.
200 Highland Avenue
Suite 301
Needham, MA 02494

Contact:

SON Medical
290 Turnpike Road, #323
Westborough, MA 01581
F. David Rothkopf

Date Prepared:

March 7, 2005

Name of Device:

Traxyz Medical Inc. TraxyLoc™-1 System

Predicate Device:

Lorad Digital Spot Mammography KS09810
Mammospot Paddle K954521

Intended Use:

The TraxyLoc™-1 System is a near-real time, image-guided accessory to mammography equipment designed to stabilize a patient's breast and assist a qualified physician in performing a pre-surgical, stereotactic needle localization procedure to target one or more mammographically previously discovered abnormalities for subsequent biopsy or other procedures.

Device Description:

The TraxyLoc™-1 System is designed for, pre-surgical use in a stereotactic needle localization of mammographically previously discovered breast abnormalities. The device provides breast stabilization and needle guidance for accurate placement of localization needles at positions of suspected abnormalities in the breast.

The device is intended for appropriately trained and qualified physicians, radiologists, and radiology/medical technicians who have previously performed manual and/or stereotactic needle localizations procedures.

The TraxyLoc™-1 System stabilizes the breast in a compression unit which is attached to the mammography equipment. After obtaining two images stereotactically (horizontal and vertical images) the previously identified breast artifact is identified and located on the Overlay Grids. The view orientation and artifact location data is then entered into the Traxalign™ software and the system settings for performing a needle localization are obtained. The localization needle is loaded into the needle holder. The needle holder is then placed onto the guidance frame as per the software directions. The needle is inserted into the breast as per a typical manual needle localization procedure. At least one confirmatory mammography image should be taken to ensure the position of the needle.

Technological Characteristics:

The technological characteristics of the new device are less than those of the predicate device.

Performance Data:

Bench testing was performed to ensure that the device performs as intended. All testing demonstrated satisfactory performance of the device.

- The image quality of the breast artifact with the device is equivalent to current standards.
- The breast stabilizer compresses the breast comfortably, does not impact image quality, and does not uncompress during the procedure.
- The software accuracy of the needle placement is +/-1mm. Note this accuracy is dependent upon accurate user data input, needle straightness, breast density and user attention to needle assembly positioning. At least one and sometimes a pair of post needle localization confirmatory X-ray images are required as part of standard practice.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 2005

Traxyz Medical, Inc.
% Mr. F. David Rothkopf
President
SON Medical
290 Turnpike Road, #323
WESTBOROUGH MA 01581

Re: K050663
Trade/Device Name: TrazyLoc™-1 System
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: March 9, 2005
Received: March 15, 2005

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050663

Device Name: **TraxyLoc™-1 System**

Intended Use:

The TraxyLoc™-1 System is a near-real time, image-guided accessory to mammography equipment designed to stabilize a patient's breast and assist a qualified physician in performing a pre-surgical, stereotactic needle localization procedure to target one or more mammographically previously discovered abnormalities for subsequent biopsy or other procedures.

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050663

Prescription Use ✓ OR Over-the-Counter Use ___
21 CFR 801.109